REMARKS

Upon entry of the present amendments, claims 1-39 will be pending. Claims 11-16 are under examination, and claims 1-10 and 17-36 stand withdrawn (as Applicants wish to retain their right to rejoinder).

Claim 12 has been amended to change the term "about 1:1" to "from 1:3 to 10:1." Support for this amendment can be found throughout the specification (*e.g.*, at page 5, line 10; at page 10, line 7; and in Example 3).

New claims 37-39 have been added by the present amendment. These claims depend from examined claim 11 and further limit the source of the cells within the composition claimed. For example, claim 37 specifies that "the hair dermal papilla cells and the active epidermal cells both originate in mice, both originate in rats or both originate in humans." As the Examiner has found that Applicants' specification *is enabling* "for select species of mammalian cell compositions," it is Applicants' position that at least new claims 37-39 are in condition for allowance and that the amendment "after final" should be entered on that basis. The new claims are supported throughout the specification (*e.g.*, at page 8, lines 15-23; at page 9, lines 18-27; and in the Examples). No new matter has been added.

Rejections Withdrawn

Applicants note with appreciation the Examiner's statement that "[a]ny rejection and/or objection not specifically addressed ... herein is withdrawn" (Office action at page 2). Accordingly, the objection to the prior phrasing of claim 12, the rejection for lack of utility, and all of the rejections under the second paragraph of 35 U.S.C. § 112 except for the rejection based on the inclusion of the term "about" in claim 12 have been withdrawn.

35 U.S.C. § 112, ¶ 1

What remains is primarily the rejection of claims 11-16 for lack of enablement. The Examiner found Applicants' arguments unpersuasive "because the instant claims are directed towards an immeasurable number of organismal or mammalian cell combinations having *a priori*

indeterminate operability, wherein only a limited number of species of cell combinations (e.g. the disclosed human, mouse, and/or rat cell combinations) are provided as having the desired function" (Office action at pages 2-3). The Examiner further states, "the specification ... does not reasonably provide enablement for all compositions" and "[t]he claims are generally drawn to a ... composition using cells from any organismal source (or combination of organisms)" (Office action at page 3).

Following these comments regarding the breadth of the claims (an important factor when analyzing enablement under *In re Wands*), the Examiner turns to the state of the art and the predictability of the art. More specifically, the Examiner reviews four publications: Inamatsu (U.S. Patent No. 5,851,831); Stenn *et al.* (*J. Invest. Dermatol.* 128:1576-1578, 2008; "Stenn"); Chuong *et al.* (*J. Invest. Dermatol.* 127:2098-2100, 2007; "Chuong"); and Ehama *et al.* (*J. Invest. Dermatol.* 127:2106-2115, 2007; "Ehama"). Chuong and Ehama are related in that Chuong is a "Commentary" of Ehama. As discussed further below, the Examiner relies on these publications in an attempt to establish that the art is unpredictable (Office action at pages 4-6).

The Examiner then recognizes that "[t]he relative skill of those in the art is high" (Office action at page 6) and notes that the specification "has provided examples of cell compositions, including those from human/murine, mouse/mouse, mouse/rat, etc." (Office action at page 6). Returning to Chuong and Ehama, the Examiner then concludes that one "would be burdened with undue experimentation" because of "the high unpredictability and the lack of guidance provided in the specification" (Office action at page 7).

The Examiner is respectfully asked to reconsider, for the following reasons.

While the claims are not limited to cells derived from any single particular organism, the claims are nevertheless limited. In fact, the compositions claimed must include two specific cell types -- hair dermal papilla cells and active epidermal cells. Thus, the source of the cells *is* limited at least somewhat; the cells cannot come from any organism, but only from an organism that has dermal papilla cells and/or epidermal cells. Further, and significantly, the cells within the composition must be subjected to the steps set out in claim 11, including the cryopreservation and mixing steps (either literally or by equivalence). Thus, the claims do not cover any and all compositions in which the recited cell types are present, but rather only those compositions prepared as set out in claim 11. The steps of the claim are several and limiting.

While it is true that there are numerous sources of hair dermal papilla cells and epidermal cells, Applicants conceived the use of cells from various sources, and their specification teaches as much. The Examiner's attention is kindly directed to the specification at page 8, lines 15-23, and page 9, lines 18-27. Moreover, the use of various cell types has been exemplified. Applicants have *demonstrated* success with rat, mouse, and human cells in various combinations (*i.e.*, mouse papilla cell + mouse epidermal cell, and rat papilla cell + rat epidermal cell (Table 4), along with two heterogeneous combinations, *i.e.,* mouse papilla cell + rat epidermal cell (Table 4), and mouse papilla cell + human epidermal cell (Table 5)). One of ordinary skill in the art could readily practice the invention with these cells, and there is nothing on the record that suggests undue experimentation would be required to use a cell from another source, say, a dog or a primate. Accordingly, the breadth of the claims is reasonable and reasonably correlated to the teaching of the specification. If the claims were limited to only the cell types Applicants have actually reduced to practice, others could make and use their invention with impunity. Such claims would not afford Applicants any reasonable protection of their invention, and that is not the intent of the patent statutes.

Regarding predictability, the rejection cannot be maintained on the basis of the prior art or the state of the art. It is simply inappropriate to determine enablement *based on methods that are wholly distinct from the methods now claimed.* Just because there may have been some difficulties *when cells were treated as described in the art* does not mean that one of ordinary skill in the art would be forced to resort to undue experimentation *to make the present compositions by the straightforward steps set out in the present claims.*

Inamatsu describes methods of culturing dermal papilla cells, but there is no mention at all of cryopreservation. Stenn is silent on any method of purifying dermal papilla cells. Ehama made compositions with two types of human cells, but Ehama's dermal papilla cells were isolated by cell culture (*see* page 2113, ¶ 3), not by cryopreservation (as Applicants discovered to be beneficial and now claim). Ehama's method may have fallen short, but that does not mean that everything in the art, including the distinct methods Applicants used, is so unpredictable that one would have to resort to undue experimentation to make and use the present compositions.

Here, the relevant factors weigh in favor of enablement. The nature of the invention is quite straightforward, and the state of the prior art is advanced. There is bound to be some

unpredictability in the art, but there is no reason why one of ordinary skill in the art would have to engage in any more experimentation to practice the present methods than would be routinely practiced in the art. A considerable amount of experimentation is permissible, if it is merely routine. MPEP at 2164.06.

As noted above, the specification provides substantial guidance. Applicants describe the purification of dermal papilla cells from mammalian tissue by cryopreservation (see, *e.g.*, the specification at page 7, line 8, to page 8, line 14) and the preparation of epidermal cells (page 9, lines 1-17). The present application also teaches the importance of mixing dermal papilla cells and epidermal cells at different ratios, and ratios are a further limitation recited in the present claims (*see* page 9, line 28, to page 10, line 12).

In view of all of the factors, Applicants respectfully submit that the claims are enabled and request that the rejection under 35 U.S.C. § 112, ¶ 1, be reconsidered and withdrawn.

35 U.S.C. § 112, ¶ 2

Claim 12 was rejected for allegedly being indefinite because "the term 'about' is a term of degree" and therefore, "'about 1:1' may reasonably be interpreted to include a broad range of dermal papilla cell:epidermal cell ratios" (Office action at page 8).

Applicants do not concede this point for several reasons, including those presented on the record. However, and solely in the interest of obtaining allowance, Applicants have amended claim 12 so that it no longer includes the term "about." This ground for rejection should now be withdrawn.

CONCLUDING FORMALITIES

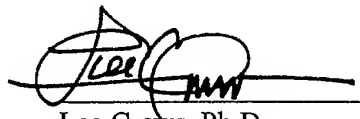
In light of the claim amendments and remarks discussed and made herein, Applicants submit that the pending claims are allowable and request early and favorable action thereon.

The fee in the amount of $490 for the Petition for Extension of Time fee is being paid on the electronic filing system by way of deposit account authorization. A Notice of Appeal, with the required fee, is being filed concurrently.

Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 23757-0009US1.

Respectfully submitted,

Date: April 20, 2009



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